Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTDC, NCI

Policy and Guidelines for
Investigational Agent Distribution

Policy: The Pharmaceutical Management Branch(PMB) provides investigational agents for use in CTEP approved protocols to registered investigators with a current signed FDA 1572 on file with the PMB. Orders will only be shipped to the shipping address indicated on the investigator's DCTDC registration form (FDA Form 1572).

Guidelines:

- **Investigational agents will be shipped from PMB directly to the institution or site where the agent will be prepared and administered.** Direct shipment of investigational agents to the preparation site simplifies agent tracking for investigators and PMB, minimizes delays in correspondence in emergencies, assures agent integrity, reduces administrative workload (maintenance of additional accountability records, drug transfer forms & correspondence) and eliminates secondary shipping expenses.

- **DCTDC supplied investigational agents must NOT be re-distributed or transferred to another institution or site, with the exception of satellite distribution (see below).**

- Satellite distribution - PMB does allow for investigational agents to be received by a centralized pharmacy area and then re-distributed to satellite areas under certain well defined circumstances:
    - Centralized pharmacy service with investigational/oncology pharmacy satellites within a single institution.
    - Medical Center Complex - Two or more institutions operating as a "centralized research base" receiving professional services from a single centralized pharmacy service. The institutions should be tied through affiliation agreements and the professional staff should be shared or have joint appointments. These institutions should be on the same campus or in close proximity (e.g. same city) to one another.
    - Institutions that are separated geographically by great distances (e.g. different cities or states) but share professional staff or have joint appointments are NOT considered satellites. Investigational agents should be shipped directly to each of these sites.
    - The centralized pharmacy service must only provide DCTDC supplied agents to investigators with a current registration on file with PMB.
    - The centralized pharmacy service is ultimately responsible for all investigational agents received and must provide copies of all accountability records during any CTEP directed audit.
    - Satellite dispensing areas must follow all Drug Accountability procedures.

- DCTDC supplied investigational agents must NOT be repackaged and forwarded by mail or overnight delivery services to another institution or site.

- In accordance with the FDA guidelines on Good Clinical Practice and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), whenever possible, the pharmacy department should be responsible for drug receipt, storage, accountability, and preparation.

- PMB recommends that all participating investigators at an institution use the same shipping (pharmacy) address.

When a number of investigators are participating on a clinical study at the same institution, one investigator should be considered or designated the principal investigator under whom all investigational agents for that protocol should be ordered.

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